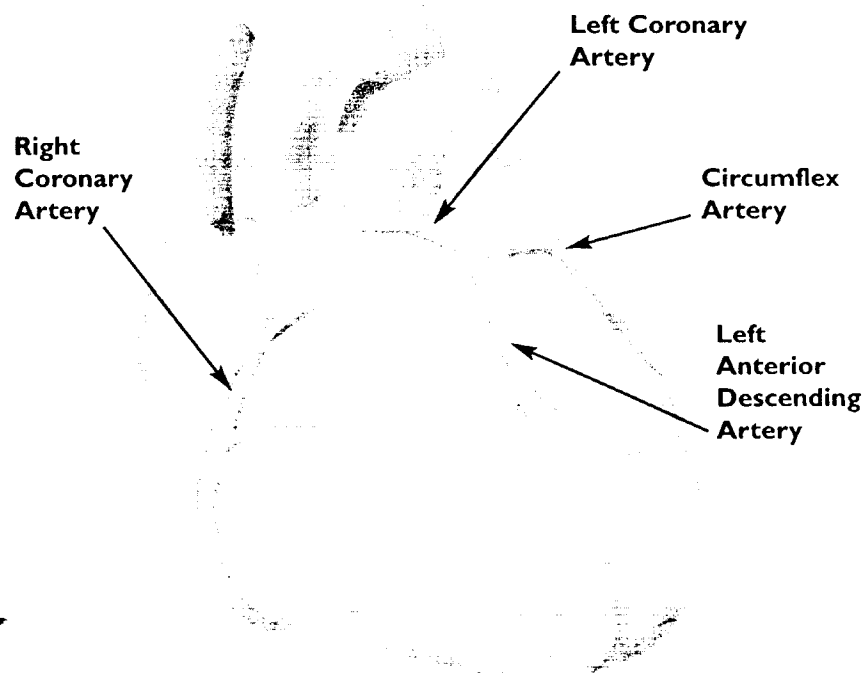


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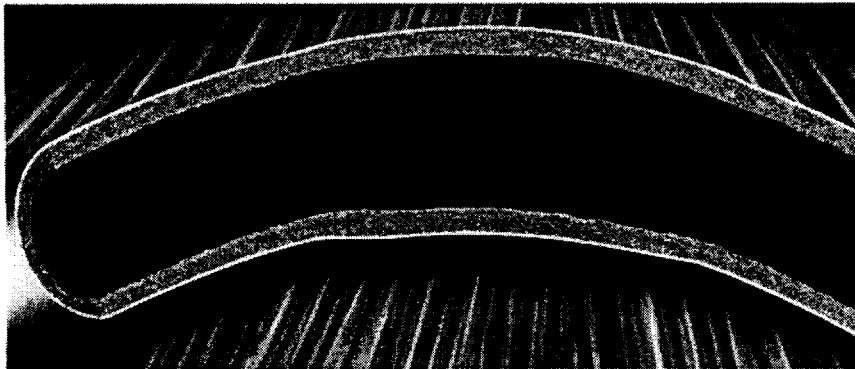
YOUR HEART

Your heart is a muscle that pumps blood through your body. The blood carries oxygen and nutrients that your body needs to work correctly. For the heart to be able to do its work it must be fed with oxygen-filled blood. The blood vessels that feed the heart muscle are called coronary arteries.

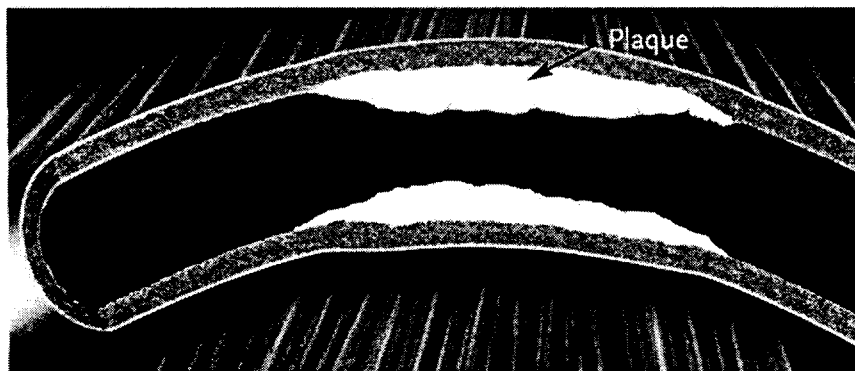


CORONARY ARTERY DISEASE

As we age, fatty deposits and/or calcium (plaque) build up on the inside of our coronary arteries. Plaque can reduce the flow of oxygen and nutrient-rich blood to the heart resulting in chest pain or angina. This disease process is known as atherosclerosis.



Healthy artery



Artery with plaque

DIAGNOSIS

When making a diagnosis, your doctor will consider the following:

- Your symptoms and
- Your risk factors, which include being overweight, smoking, having high cholesterol and family history of coronary artery disease.

Tests such as an electrocardiogram (ECG) or coronary arteriogram (angiogram) help your physician diagnose the problem.

THE CORONARY ANGIOGRAM

Your doctor may perform a special x-ray test called a coronary angiogram, also called a “heart catheterization”, to look for narrowed or blocked coronary arteries. This test is performed in the cardiac catheterization laboratory (cath lab), a room designed especially for this procedure. This test takes between 20 and 40 minutes.

During the procedure the catheter lab staff and your doctor will:

- Insert a small intravenous (IV) tube into your arm. This IV allows fluids and medications to be given to you.
- Place small sticky patches (electrodes) on your chest to monitor your heart rate and rhythm.
- Give you a mild sedative to help you relax.
- Shave and wash the area where the heart catheter will be inserted (your groin or arm).
- Cover your body with sterile sheets.
- Use medication to numb the area that has been cleansed.
- Insert a hollow tube into the artery in your groin or arm. Through this hollow tube, the doctor can move guidewires and catheters to the arteries in your heart.
- Inject a special x-ray dye through the tube to allow your doctor to see the arteries of your heart on an x-ray monitor, much like a television screen.
- Ask you to take a deep breath and hold it for a few seconds as the x-rays are taken. You may be asked to cough after the x-rays are taken, to clear the dye from the coronary arteries.

Tell your doctor or nurse if you feel any pain during the procedure.

You will go to a recovery area after the angiogram for monitoring before returning to your hospital room or going home.

TREATMENT FOR CORONARY ARTERY DISEASE

Each year many patients with coronary artery disease need treatment to increase the flow of blood to the heart. Treatment may include drug therapy, surgery, angioplasty or stenting

DRUGS

Drugs work to expand the coronary arteries, increasing the flow of blood to that portion of your heart.

SURGERY

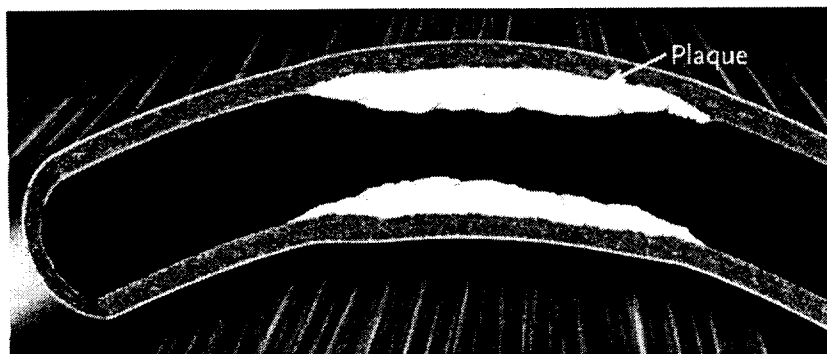
Coronary Artery Bypass Grafting (CABG) is performed during surgery. An artery from your chest or a vein from your leg may be used to pass around (bypass) the narrowed or blocked part of the artery and resume the flow of blood to your heart.

BALLOON ANGIOPLASTY (PTCA)

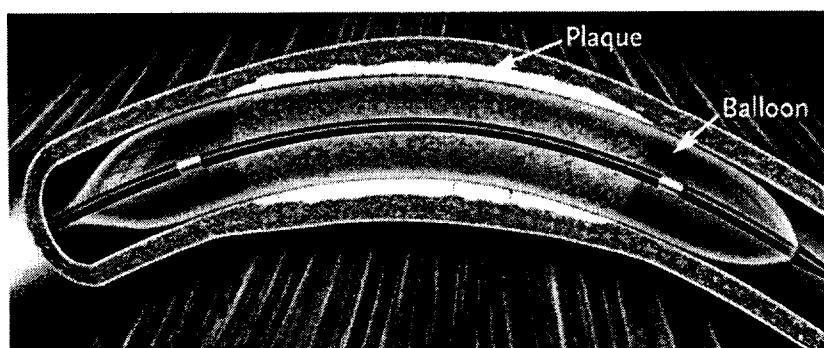
Balloon Angioplasty is a procedure that uses a catheter with a small balloon on it. The balloon is inflated to push apart the plaque in the clogged arteries. This makes the blood flow in the artery increase.

It is normal to have some chest pain when the balloon is inflated. Tell your doctor or nurse if you feel any pain during the procedure.

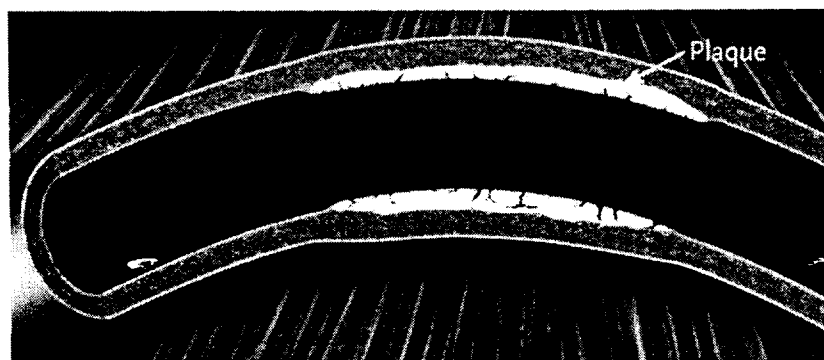
PTCA
(Percutaneous Transluminal Coronary Angioplasty)



Before: PTCA narrowing



Balloon inflated



After: PTCA enlarged lumen

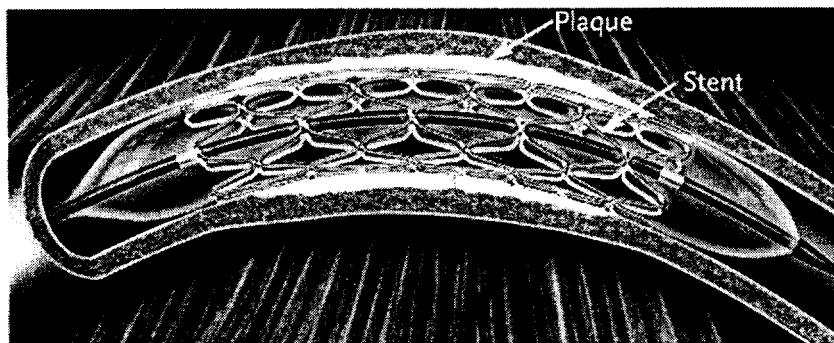
STENTING

Your doctor may recommend placing a coronary stent in the diseased area. A stent is a wire mesh tube that acts as a scaffold inside the artery. The stent is placed on a specially designed balloon catheter which takes it to the diseased area.

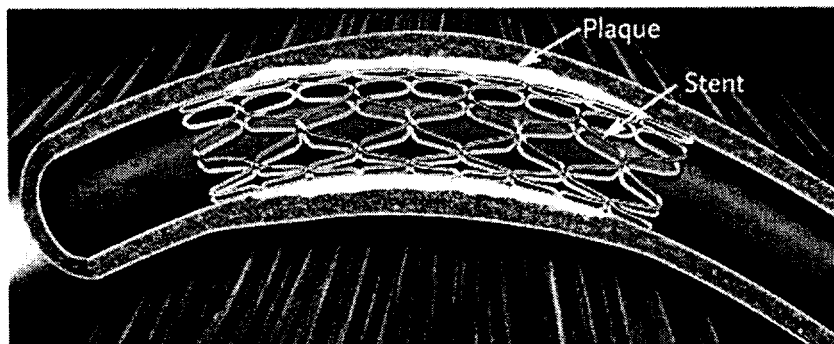
The balloon is inflated to spread out the stent and flatten plaque against the artery wall. This increases blood flow by holding the artery wall open.

Once the stent is fully opened, the balloon is deflated and removed. The stent stays in your artery permanently. It may be necessary to place more than one stent, depending on how much of your artery is blocked.

Stents should be implanted in hospitals where emergency coronary artery bypass graft procedures can be performed.



Stent with balloon inflated



Balloon withdrawn, stent implanted

The inside lining of the artery will grow over the stent in about eight weeks.

THE MEDTRONIC DRIVER CORONARY STENT

Medtronic Driver coronary stents are made of a medical-grade metal alloy with cobalt, chromium, molybdenum and nickel. Each stent is polished for a smooth surface and shaped to allow it to pass through your arteries on a specially designed balloon catheter.

When multiple stents are required, stent materials should be of similar composition. Placing multiple stents of different metals in contact with each other may increase the potential for corrosion.

Patients who received the Driver stent during a US clinical trial were followed for nine months after the stent was implanted; therefore outcomes beyond 9 months for this permanent implant are unknown at this time.

POSSIBLE RISKS

There are unexpected incidents that **MAY** happen with the use of medical devices and or the procedure used to deliver them. These may happen during or after placement of a coronary stent in your heart.

Possible risks may include:

- Re-narrowing of the heart artery which may require a repeat procedure to re-open the heart artery, the long-term outcome of which is unknown at present
- Patients who are allergic to cobalt chromium (Co-Cr) or nickel based metals may experience an allergic reaction to this implant
- Patient who cannot take aspirin or blood thinners (anticoagulants) should not have this procedure.
- Patients who have a blockage in their artery, which prevents complete inflation of an angioplasty balloon, should not have this procedure.

Other risks are:

- Bruise or bleeding at the catheter insertion site in the groin or arm
- Pain at the catheter insertion site
- Irregular heart beats
- Chest pains during and after the procedure
- Decreased or increased blood pressure
- Tearing, puncture or rupture of the heart artery
- Air, pieces of devices or fragments of clots blocking the coronary artery
- Complete blockage of the heart artery which may require a repeat procedure to re-open the heart artery the long-term outcome of which is unknown at present
- Bleeding around the heart

- Heart attack
- Damage to the stent or injury to the coronary artery requiring emergency heart surgery
- Bleeding requiring transfusion or surgery
- Allergic reaction [may include x-ray dye, drugs, stent metal (cobalt, chromium, nickel)].
- Infection
- Nerve injury
- Aneurysm (weakening of a portion of the wall of a blood vessel)
- Failure to release the stent from the catheter
- Stent misplacement in the artery
- Movement of the stent from where it was placed
- The balloon used to expand the stent may break
- Shock
- Stroke
- Death

Talk to your health care professional about the risks and benefits of coronary artery stenting.

AFTER YOUR STENT PROCEDURE

You will be asked to lie flat for four to six hours following the procedure and not bend your leg or arm, depending on which area your doctor used to insert the catheters. Pressure will also be placed on the area.

You may have a vascular closure device to seal the puncture site in your groin or arm. You will be allowed to get up and walk around sooner if this type of device is used. Your hospital stay may range from one to three days.

You may need to take medications before and after stent placement. Aspirin and “platelet inhibitors” are the most commonly prescribed. Their purpose is to prevent a blood clot (thrombus).

You may need to have periodic blood tests while taking these medications,. Your doctor or nurse will give you instructions about your medications before you leave the hospital.

It is very important that you take all of your medications until your doctor tells you to stop them.

GOING HOME FROM THE HOSPITAL

Your family doctor and cardiologist will follow your progress after you leave the hospital.

If you have any chest pain, discomfort or bleeding from your puncture site, call your doctor immediately. If your doctor is unavailable, call 911 to take you to the nearest hospital emergency room.

MRI INFORMATION

If you require a magnetic resonance imaging (MRI) scan, the Driver Coronary Stent has been shown to be MRI safe immediately following implantation at a field strength of up to 1.5 Tesla. MR imaging may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

You should discuss any questions you may have about this with your health care provider.

Further information about MRI and the Driver stent can be found in the Instructions for Use accompanying the product or by contacting Customer Service at (888) 283-7868.

DEFINITIONS

Angina - Pain or discomfort in the chest because of reduced blood and oxygen flow to the heart muscle.

Angioplasty - The opening of a narrowed or blocked artery with specially designed balloon catheters.

Atherosclerosis - The process of fatty deposits and/or calcim build-up (plaque) on the inside of the coronary arteries.

Contrast - X-ray dye used to view the coronary arteries during coronary angiogram.

Coronary angiogram - A procedure in which dye is injected into the coronary arteries to diagnose a narrowing or blockage of the artery.

Coronary arteries - The blood vessels that bring blood to the heart.

Medical grade alloy – A special type of metal used for making medical products that are placed (implanted) in the body.

MRI (magnetic resonance imaging): Test that uses magnetic waves to obtain images of the inside of your body.

Platelet inhibitors: Medications to prevent blood cells called platelets from sticking together and blocking the artery.

Restenosis - Repeat narrowing or blockage in an artery after treatment.

Thrombus - Blood clot.

Vascular closure devices – Products used to seal or close the artery puncture after angiogram or angioplasty. Made from either collagen plugs (special fiber that seals the puncture site) or internal sutures (stitches).

X-ray dye → A liquid that is visible with x-ray

NOTE PAGES

DRIVER CORONARY STENT IMPLANT CARD

Medtronic, Inc.

Coronary Technologies

3576 Unocal Place .

Santa Rosa, CA 95405

Tel. (707) 525-0111

Fax (707) 525-0114

Product code(s)

Lot Numbers

_____	_____
_____	_____
_____	_____

Instructions:

Please carry this card at all times and show it to any medical personnel who may be treating you.

If you require a magnetic resonance imaging (MRI) scan, the Driver Coronary Stent has been shown to be MRI safe immediately following implantation at a field strength of up to 1.5 Tesla. MR imaging may be compromised if the area of interest is in the exact same area or relatively close to the position of the stent.

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Patient name _____

Date of Implant: _____

Coronary artery(ies) treated: _____

Implanting Physician: _____

Telephone: _____

Implanting Hospital: _____